Claims Amendment

Please enter the amendments to pending Claim 1, and 5-9, and new Claims 11-13, as shown in the appended marked-up listing thereof. All claims are presented below in the format specified under revised 37 C.F.R. § 1.121. This listing of claims will replace all prior versions, and listings, of claims in the application. No new matter is deemed to have been added by the amended claims.

REMARKS

Claim Objection

Applicant has amended independent claim 1 by, *inter alia*, adopting the clarifying language suggested by the Examiner. Applicant has further amended claim 1, and claims 5-9, to better clarify that the various dosages, apart from the enteric coated oral EDTA dosage, are taken daily and that each of the additional dosage forms comprise a distinct aspect of the nutritional protocol of the claimed invention.

The Examiner's courtesy in offering clarifying language for claim 1 is acknowledged with appreciation.

Claims Rejections – 35 USC § 103

Applicant has amended independent claim 1 and dependent claims 5-9, and added new claims 11-13. As amended, independent claim 1, and claims 2-9 and 11-13 that depend therefrom, are non-obvious in view of the cited prior art.

The subject invention is a "wellness oriented nutritional supplement and protocol which provides antimicrobial and antitoxin action as an adjunct to vitamin and mineral supplementation. . ." Specification, ¶ 3. "The invention embraces both the individual compositions and the treatment protocol with one or more of the four stages." *Ibid.*, ¶¶ 4 & 12.

Section 103 Legal Standard

> Whereas, in a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made.

MPEP, § 706.02 V.

> "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

MPEP § 706.02(j).

Claims 1 through 3

Amended independent claim 1 teaches a nutritional supplement protocol comprising an EDTA containing mouthwash and an enteric coated EDTA containing oral pharmaceutical, wherein mouthwash is practiced daily and the oral pharmaceutical is ingested at least five days of each seven day period.

Rozema teaches an intravenous protocol for the administration of EDTA and other chelating agents as treatment of vascular disease, degenerative disease and metal toxicity. Rozema teaches away from the administration of EDTA as an oral pharmaceutical and also away from a protocol that incorporates an EDTA containing mouthwash:

> Only about 5% of an orally administered dose of EDTA is absorbed from the gastrointestinal tract although this may vary with the contents of the digestive tract. The bulk is excreted in the stool, thus this route of administration is much less physiologically effective than the same dose administered intravenously.
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> * * *
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> Therefore the most effective route of administration for most of the currently recognized clinical benefits appears to be intravenous.

Rozema, at 16.

Rozema teaches daily EDTA dosages of 50 to 200 mg for intravenous use. Rozema does not teach daily EDTA dosages for administration as an oral pharmaceutical.

Rozema teaches adding Vitamin C to the infusion bottle containing EDTA for intravenous administration. Rozema does not teach combining Vitamin C with EDTA for oral administration or for use as a mouthwash.

Rozema does not teach a protocol comprising the administration of EDTA internally together an EDTA solution practiced as a mouthwash.

Kotilainen teaches a mouthwash solution practiced twice daily containing water soluble alkali metal or alkali earth metal salts, including EDTA, to prevent the build up in the oral cavity of metals and in particular of heavy metals. Kotilainen does not teach the use of EDTA internally. Kotilainen does not teach the use of EDTA as a mouth wash together with Vitamin C.

It would not have been obvious to one skilled in the art to combine the teachings of Kotilainen with Rozema. Neither publication suggests such a combination. Rozema concerns itself with the treatment of systemic diseases such as vascular disease and metal toxicity. In contrast, Kotilainen restricts itself to oral hygiene and gum and teeth health. Rozema teaches away from the oral administration of EDTA. Kotilainen does not teach, suggest or contemplate the internal use of EDTA. It would be illogical to combine teachings from one publication with the other, absent the hindsight gained from Applicant's disclosure.

> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)
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> * * *
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> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)([Wherein t]he court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

MPEP § 2143.01 V. & VI.

Claims 5-8

Claims 5 through 7 teach a nutritional supplement protocol comprising an EDTA containing mouthwash practiced together with an enteric coated EDTA containing oral pharmaceutical practiced together with a phosphatidyl lipids oral pharmaceutical that optionally contains alpha lipoic acid.

Hsia teaches a composition and method for treating nonalcoholic steatohepatitis comprising lecithin, antioxidants and vitamin B complex administered orally. Lecithin is among the group known as phosphatidyl lipids. Hsia does not teach the use of lecithin or other phosphatidyl lipid in absence of an antioxidant and vitamin B complex. Hsia does not teach the use of lecithin administered orally together with a mouthwash, or together with the oral administration of EDTA.

The composition and method of Hsia is specific for treating nonalcoholic steatohepatitis, a condition different and distinct from those targeted by the intravenous administration of EDTA in Rozema, from the plaque and gum disease intended to be addressed by the mouthwash of Kotilainen, and from the antimicrobial and antitoxin action provided by the claimed invention. There is no suggestion within each of these prior art publication for the combination being proposed by the Examiner, nor is there any logical basis to assume one skilled in the relevant art would be motivated to make the combination. See MPEP § 2143.01 V. & VI quoted above and the authority cited therein.

Considering the Claimed Invention as a Whole and the Prior Art in Their Entirety, the Instant Invention is Not Obvious

> In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983).
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> * * *
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> A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

MPEP § 2141.02 I. & VI.

The invention here "embraces both the individual compositions and the treatment protocol with one or more of the four stages." Specification, ¶¶ 4 & 12. Independent claim 1 combines two of the four stages. None of the cited prior art teach, suggest or imply a protocol having more than one stage. None teach, suggest or imply a protocol that combines a mouthwash with an oral pharmaceutical. "All words in a claim must be

considered in judging the patentability of that claim against the prior art." MPEP § 2141.02, citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)."

Viewing the invention defined by independent claim 1as a whole, and considering the prior art publications in their entireties, whether separately or in combination with one another, the claimed invention is not rendered obvious.

Conclusion

"If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." MPEP § 2143.03.

Pending claims 2 through 9 and 11 through 13 include all limitations of amended independent claim 1. According claim 1, as amended, and claims 2 through 9 and 11 through 13 are unobvious in view of Rozema alone or Rozema in combination with Kotilainen.

CONCLUSION

In light of the remarks, authority and evidence presented above, and the amended claims listing set forth below, Applicant submits that all claims currently pending in the application, being apparatus claims 1-9 and 11 through 13, should be allowed. Applicant further submits that it should be given the opportunity to amend apparatus claim 10 to include all limitations of amended method claim 1 such that apparatus claim 10 may be rejoined with the allowed apparatus claims in accordance with MPEP § 821.04.

This Amendment and Response is being electronically transmitted via EFS-Web this day HST (expected receipt on October 22, 2009), within three (3) months of the issue date of the July 23, 2009 office action, and no extension fees are due. The amended claims are within the number originally paid for, and no further fees are due as a result of the proposed claims amendments.

The Examiner is invited to contact the undersigned attorney at (808) 521-7080, business hours Hawaii standard time, or via email at <seth.reiss@lex-ip.com>, in order that the undersigned attorney may endeavor to resolve any outstanding issues as expeditiously as possible thereby to avoid prolonged prosecution of the present application.

Respectfully submitted,

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